

7-28-04

A S11617 \$.
ZFWBeiersdorf 596.2-HCL
100718-20
6713-Dr. Wi-ar

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

APPLICANTS : BLECKMANN et al.
SERIAL NO. : 09/436,171
FILED : 9 November 1999
FOR : PREPARATIONS OF THE W/O EMULSION TYPE WITH AN
INCREASED WATER CONTENT, AND COMPRISING CATIONIC
POLYMERS
ART UNIT : 1617
EXAMINER : Gina C. Yu

27 July 2004

Mail Stop: Appeal Brief
Hon. Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' BRIEF ON APPEAL PURSUANT TO 37 CFR § 1.192

SIR:

This is an appeal from the final rejection dated 27 April 2004.

(1) REAL PARTY IN INTEREST

The real party in interest is **Beiersdorf AG** by virtue of an assignment recorded on at Reel 010389, Frame 0193 (Recorded on 9 November 1999).

(2) RELATED APPEALS AND INTERFERENCES

There are no related appeals and interferences.

07/30/2004 AWONDAF1 00000036 141263 09436171

01 FC:1402 330.00 DA

(3) STATUS OF CLAIMS

Claims 1, 3-5, 7-9 and 11 stand rejected.

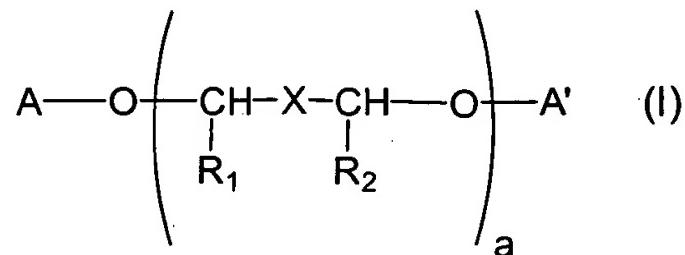
(4) STATUS OF AMENDMENTS

It is believed that all claim amendments have been entered (Note: No claim amendments were made as part of the after final response of 27 April 2004)

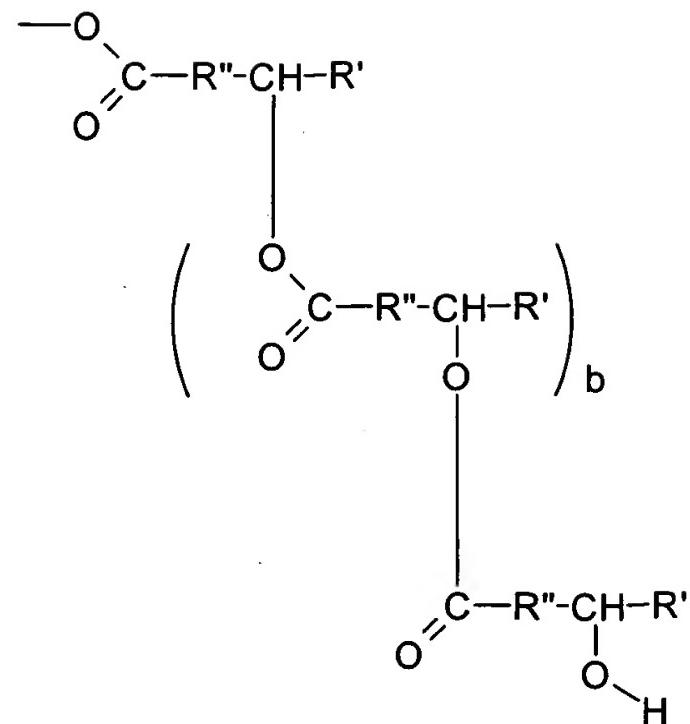
(5) SUMMARY OF INVENTION

The present invention relates to a water-in-oil emulsion

- (a) with a content of water and optionally water-soluble substances totalling greater than 85% by weight, and with a content of lipids, emulsifiers and lipophilic constituents of less than 15% by weight, in each case based on the total weight of the preparations,
- (b) comprising at least one surface-active substance selected from the group consisting of substances of the general formula (I)

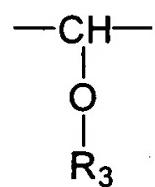


- where A and A' are identical or different organic radicals selected from the group consisting of branched and unbranched, saturated and unsaturated alkyl and acyl radicals and hydroxyacyl radicals having 10 - 30 carbon atoms, and the group consisting of hydroxyacyl groups bonded together via ester functions, according to the scheme



where R' is selected from the group consisting of branched and unbranched alkyl groups having 1 to 20 carbon atoms, and R is selected from the group consisting of branched and unbranched alkylene groups having 1 to 20 carbon atoms, and b is a number from 0 to 200,

- a is a number from 1 to 100,
- X is a single bond or the group



- R₁ and R₂ independently of one another are selected from the group consisting of H and methyl,
 - R₃ is selected from the group consisting of H, and of branched and unbranched, saturated and unsaturated alkyl- and acyl radicals having 1 - 20 carbon atoms,
- (c) additionally comprising at least one cationic polymer, wherein said at least one cationic polymer is selected from the group consisting of cationic cellulose derivatized with a

quaternary ammonium salt, cationic starch, copolymers of diallylammonium salts and acrylamides, quaternized vinylpyrrolidone/ vinylimidazole polymers, condensation products of a polyglycol with an amine, quaternized collagen polypeptides, quaternized wheat polypeptides, polyethyleneimine, cationic silicone polymers, copolymers of adipic acid with dimethylaminohydroxypropylidethylenetriamine, copolymers of acrylic acid with dimethyldiallylammonium chloride, polyaminopolyamides, and cationic guar gum,

which is represented by claim 1. Support for this invention can be found e.g. in original claim 1 and in paragraph [0032] of the U.S. publication for this application (U.S. Patent Application Publication 2002-0146438). Support for the surface active substance being polyethylene glycol-30 dihydroxystearate (claim 3) can be found e.g. in the Examples cited. Support for the constitution of the oil phase (claim 4) can be found e.g. in paragraph [0054]. Support for the value of the variable a (claims 7 and 8) can be found e.g. in paragraph [0022]. The amount of cationic polymers represented in claims 5 and claim 9 are supported within the specification at paragraph [0031]. The cationic polymer being polyquaternium-10 is supported most expressly by Examples 2, 4 and 5 in the specification.

(6) ISSUES

There are two issues for consideration:

- (1) Whether claims 1, 3-5, 7-9 and 11 are obvious in light of Schreiber et al. (WO 98/17232 - now U.S. Patent 6,613,338) in view of Dupuis et al. (U.S. Patent 6,338,858); and
- (2) Whether claim 4 is obvious in light of Schreiber et al., Dupuis et al. further in view of Yoneyama (U.S. Patent 5,015,469)

Note: Since Schreiber (WO 98/17232) was written in German, all references by the appellant to specific passages for Schreiber are made with respect to the corresponding '338 patent as this is in the English language and is substantially the same as WO 98/17232.

(7) GROUPING OF CLAIMS

The claims on appeal are all ultimately dependent upon independent claim 1. However,

while it is believed that claims 1, 3, 5, 7-9 and 11 stand and fall together, claim 4 should be considered on its own merits and likewise.

(8) ARGUMENT

Background

The assignee for the Schreiber reference, Beiersdorf AG, is the same assignee as the present invention and was directed toward water-in-oil cosmetic and skin care **sticks** with a high percentage of aqueous phase (30 - 85% aqueous phase by weight). The present invention discloses that “the preparation of stable, flowable water-in-oil emulsions having a water content of more than 70% has proven to be very difficult. In particular, ‘high internal phase’ W/O emulsions with a very high water content of more than 85% (‘very high internal phase’ W/O emulsion) are not accessible.” (see page 3, lines 10-13 of specification).

In addition, “[t]he technique of varying phase/volume ratio (i.e. of incorporating higher amounts of liquid lipids), which is usually used for water-in-oil emulsions, can, because of the low lipid content...not [be used] at all in the case of ‘very high internal phase’ W/O emulsions.” (see page 3, lines 23-26 of specification)

The appellants invention, unlike the prior art, teaches water-in-oil emulsions which are able to exceed the 85% by weight aqueous phase ceiling previously thought to be inaccessible. While not wishing to be bound by theory, the use of cationic polymers appears to assist in achieving water-in-oil emulsion which are able to exceed the 85% by weight aqueous phase ceiling.

The fundamental difference between the Examiner’s position and that of the appellants’ position is the answer to the question as to whether the Examiner has established a *prima facie* case of obviousness. The Examiner believes that she has while the appellants’ believe she has not.

It is well known that “[p]rima facie obviousness in ex parte prosecution is a procedural mechanism to orderly allocate the burdens of going forward and of persuasion between the examiner and the applicant in reaching an ultimate decision on obviousness. It requires not only that the evidence of the prior art would reasonably allow the examiner to reach a conclusion of obviousness, **but also that the prior art compels such a conclusion** if the applicant produces no rebuttal evidence or argument.” see *In re Spada*, 15 USPQ2d 1655 (Fed. Cir. 1990); *In re Piasecki*, 223 USPQ 785 (Fed. Cir. 1984)

(emphasis added). The Examiner's rejection has never shifted the burden back to the appellants nor have the rejections been formed to the point where one of reasonable skill in the art would believe that the prior art cited would "compel a conclusion" of obviousness as will be established below.

Standard of Review

(1) MPEP 2141 states in part that "Office [PTO] policy is to follow *Graham v. John Deere Co.* in the consideration and determination of obviousness under 35 U.S.C 103...the four factual inquiries enunciated therein as background for determining obviousness are as follows:

- (A) Determining the scope and contents of the prior art;
- (B) Ascertaining the differences between the prior art and the claims in issue;
- (C) Resolving the level of ordinary skill in the art; and
- (D) Evaluating evidence of secondary considerations."

(2) MPEP 2141 further states that:

"When applying 35 U.S.C. 103, the following tenets of patent law **must be adhered to**:

- (A) The claimed invention must be considered as a whole;
- (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;
- (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and
- (D) Reasonable expectation of success is the standard with which obviousness is determined

Hodosh v. Block Drug Co., Inc. 786 F.2d 1136, 1143, n.5, 229 USPQ 187 n.5 (Fed. Cir. 1986)." .

(emphasis added).

Analysis as applied to the rejection of claims 1, 3, 5, 7-9 and 11 (Schreiber in view of Dupuis)

(1) *Graham v. Deere* factors

Given that the appellants' invention and that of Schreiber share the same assignee, it is not surprising that there are several similarities between the inventions. However, Schreiber differs from the appellants' invention in that Schreiber does not teach:

- (i) having an aqueous phase greater than 85% by weight;
- (ii) the inclusion of at least one cationic polymer in their stick compositions.

(2) Tenets of Patent Law

(a) Considering the claimed invention as a whole

The appellants' invention is directed toward a water-in-oil emulsion which is an improvement in the prior art in that the aqueous phase is greater than 85% by weight and that this emulsion evidently is possible by the inclusion of cationic polymers.

(b1) Considering the references as a whole

The key inventive concepts of the Schreiber and Dupuis references are highlighted below and serve as the basis upon which what one of ordinary skill in the art would have had before them for considerations of obviousness in light of the fact that the skilled artisan would not have had the appellants claims before them to act as a template.

Schreiber	Dupuis
<p>Lipsticks, antiacne sticks, sunscreen sticks and eyeshadow sticks, with a high water content, characterized in that they comprise</p> <p>(a) a lipid phase, which comprises (a1) at least one oil component (a2) at least one wax component (a3) optionally other substances soluble or dispersible in the lipid phase,</p> <p>(b) an aqueous phase, which comprises (b1) from 30 to 85% by weight of water, based on the total weight of the stick composition and (b2) if desired, substances soluble or dispersible in water,</p> <p>(c) at least one active ingredient or several chosen from the active ingredients known for lipsticks, antiacne sticks, sunscreen sticks and eyeshadow sticks,</p> <p>(d) a W/O emulsifier or a mixture of two or more W/O emulsifiers,</p> <p>(e) one or more stabilizers, chosen from the group of substances of the general structure A--B--A', where A and A' are identical or different hydrophobic organic radicals, and B is a hydrophilic group, (f) if desired, further surface-active substances as coemulsifiers, and also, if desired, stabilizers and further customary cosmetic and/or pharmaceutical auxiliaries, active ingredients and/or additives.</p>	<p>An aqueous solid topical composition comprising a matrix, i.e., an aqueous solid matrix, having the appearance of a gel and possessing the following rheological profile: an initial viscosity at rest V_0 sufficient to form a solid composition, preferably ranging from 50,000 to 1,000,000 Pa.s, said viscosity $V_{sub.0}$ being stable up to a shear strain C_1, a viscosity V_2 after shear at a strain C_2 for which the ratio V_0/V_2 is greater than or equal to 1000:1, the difference $C_2 - C_1$ being less than or equal to 1000 Pa, and which may be useful as a make-up, styling, body hygiene or care composition.</p>

Notice that Schreiber and Dupuis are both directed toward **stick** formulation with the former clearly being directed toward water-in-oil emulsions while the latter is not as clearly directed (see col. 5, lines 52-57 of Dupuis, i.e. Dupuis is more clearly directed toward gel compositions not emulsions).

(b2) Desirability to combine the references

Even if there was the requisite motivation to combine the references, the difference of having an aqueous phase greater than 85% by weight still is not addressed by the combination of references and on this basis alone, there is no *prima facie* holding of obviousness.

Although there is the potential for overlap if the appellants' invention and that of Schreiber and Dupuis are all water-in-oil emulsions, the fact that Schreiber and Dupuis are directed toward stick preparation (e.g. lipsticks, deodorant sticks, etc.) would appear to place a cap on the amount of aqueous phase that is possible in their respective formulations while maintaining the integrity of their respective stick preparations (by way of extreme illustration, one of ordinary skill in the would not expect that a lipstick formulation would be possible with a formulation comprising 99% aqueous phase and 1% lipid phase). Schreiber caps the amount of aqueous phase at an amount less than that claimed by the appellants and Dupuis discloses nothing that would suggest increasing the amount of aqueous phase beyond 85% by weight even if could be shown that Dupuis suggested the inclusion of cationic polymers to Schreiber. To the extent that it may be argued that Dupuis does teach higher than 85% aqueous phase, this would only be for their aqueous gel compositions not for any teaching of a water-in-oil emulsion.

Given that the appellants have indicated the state of the art is such that 'high internal phase' W/O emulsions with a very high water content of more than 85% ('very high internal phase' W/O emulsion) are not accessible." (see page 3, lines 10-13 of specification), and that no countervailing facts were presented by the Examiner for her to rely on the upper limit of Schreiber (i.e. 85%) as being equivalent to or rendering obvious the appellants' limitation of "more than 85%", the collective references of Schreiber and Dupuis.

To this point, the appellants have presumed that inclusion of Dupuis' isolated teaching with respect to cationic polymers is permitted. However, The discussion on obviousness in *In re Fine* closely adheres to the position maintained by the applicants and is reproduced in part below:

"Obviousness is tested by 'what the combined teachings of the references would have suggested to those of ordinary skill in the art.' *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). But it 'cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination.' ACS Hosp. Sys., 732 F.2d at 1577, 221 USPQ at 933. And 'teachings of references can be combined *only* if there is some suggestion or incentive to do so.' *Id.* Here the prior art contains none.

Instead, the Examiner relies on hindsight in reaching his obviousness determination...

It is essential that 'the decisionmaker forget what he or she has been taught at trial about the claimed invention and cast the mind back to the time the invention was made...to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art.' *Id.* One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fine*, 5 USPQ2d 1596, 1599, 1600 (Fed. Cir. 1988).

While the Examiner notes the teaching of cationic polymers as conditioners from Dupuis, she is merely reciting a property of the cationic polymer and this does not constitute a "teaching or suggestion" to combine this element with the elements of Schreiber's invention, i.e. the Examiner's recited motivation for combination stems from her own opinion and does not arise from the teachings of the prior art themselves. One of ordinary skill in the art presented with the references but without the appellants' claims as a template would not have foreseen the combination suggested by the Examiner.

(c) Impermissible Hindsight

As alluded to above, the appellants believe that the Examiner has engaged in hindsight reconstruction to combine the references in order to establish her *prima facie*

case of obviousness. The appellants continue to hold that the Examiner has merely attempted to acquire the necessary elements to establish her case of *prima facie* obviousness without consideration as to whether the separate elements can properly be combined.

It is well known that merely collecting the elements of the applicants' invention is insufficient to establish a *prima facie* case of obviousness. As stated in *In re Rouffet*, 149 F.3d 1350, 47 USPQ2d 1453 (Fed. Cir. 1998):

"virtually all [inventions] are combinations of old elements...***Therefore an examiner may often find every element of a claimed invention in the prior art.*** If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat patentability of the claimed invention. ***Such an approach would be 'an illogical and inappropriate process by which to determine patentability.'*** *Sensotronics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1570, 38 USPQ2d 1551, 1554 (Fed. Cir. 1996)." *Rouffet*, 149 F.3d at 1357, 47 USPQ2d 1457 (emphasis added).

The conclusions drawn by the Examiner could only be made if one of ordinary skill in the art had had the appellants' claims before them to act as a roadmap to the invention.

Reviewing again the chart on page 7 of this brief, consideration of the teachings of Schreiber and Dupuis as a whole does not lead one of ordinary skill in the art to the use of cationic polymers or to combine them into a water-in-oil emulsion or suggest that such a combination would result in water-in-oil emulsions which have an aqueous phase content of greater than 85% by weight, i.e. there is no reason for one of ordinary skill in the art to magically select the cationic polymer portion of the teaching of Dupuis to the exclusion of all the other critical and non-critical elements of Dupuis' invention. As stated in *In re Fine* above "One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *Id.* at 1600. However, this is precisely what the Examiner has done.

The Examiner's response in her Advisory Action appears to indicate confusion about the nature of the "picking and choosing" argument; the appellants do not deny that

Dupuis "unambiguously" discloses cationic polymers. However, the standard is why one of ordinary skill in the art would have been motivated to select this non-essential element from the teaching of Dupuis to the exclusion of their invention as a whole and combine it with the teachings of the Schreiber reference which is directed to a totally different form of stick preparation, i.e. it is ambiguous in that among the various permutations of the Dupuis invention, one of ordinary skill in the art would not clearly be directed to select only this portion of the teaching in Dupuis.

(d) **Expectation of success**

Even if the Examiner were permitted to engage in hindsight reconstruction, there is still no factual evidence that it was possible to exceed the 85% by weight aqueous phase for a water-in-oil emulsion based on the teachings of Schreiber and Dupuis.

Analysis as applied to the rejection of claim 4 (Schreiber in view of Dupuis and Yoneyama)

The appellants arguments with respect to claims 1, 3, 5, 7-9 and 11 made above against Schreiber in view of Dupuis are to be considered repeated here and is supplemented by the following points.

(1) *Graham v. Deer factors*

The Yoneyama reference is relied upon for their teaching of the composition of the lipid phase which was acknowledged by the Examiner not to have been taught by the combination of Schreiber and Dupuis.

(2) **Tenets of Patent Law**

(b1) **Considering the references as a whole**

Yoneyama is also a water-in-oil emulsion and does teach a composition of oil phase which is similar to that claimed by the appellants claim 4. However, this is within the context of providing an emulsion with at least four or five separate elements (summarized for brevity - see claim 1 or col. 2, "Summary of the Invention"):

- (i) water-swellable clay material
- (ii) a non-ionic surfactant
- (iii) an oil component
- (iv) water;

(not apparently relied upon by the Examiner)

or

- (i) water-swellable clay material
- (ii) a quaternary ammonium salt type cationic surfactant
- (iii) one or two or more kinds of polyoxyalkylene modified organopolysiloxane
- (iv) an aqueous phase
- (v) an oil phase containing one or two or more kinds of organic silicone resin.

The cationic surfactants of (ii) are not polymers as in the appellants' claims (see col. 5, lines 18-55) and from further reading it can be seen that elements (ii) and (iii) depend on the relative amounts of clay material (i).

Such that Yoneyama could be argued to teach a water-in-emulsion which possesses more than 85% by weight aqueous phase (see claim 1). However, each of Yoneyama's Examples possess less than 85% aqueous phase and there is no indication that they were able to overcome the limitations of the art as described by the appellants in their specification. Even if were somehow shown that Yoneyama could make water-in-oil emulsions with greater than 85% aqueous phase, the value of such a teaching would be limited to the combination of the specific elements cited by Yoneyama.

(b2) Desirability to combine the references

Again, it is unclear why or how one of ordinary skill in the art when presented with Yoneyama in addition to Schreiber and Dupuis would have known to select only the oil phase teaching portion of Yoneyama to combine with Schreiber absent any further guidance (e.g. why wouldn't the skilled artisan choose only the teaching of water-swellable clay instead which appears to be the main focus of Yoneyama's invention?).

(c) Impermissible hindsight

Again, selecting only the teaching of the oil phase from Yoneyama to combine with Schreiber and Dupuis is indicative of merely finding a requisite element and then resorting to improper "picking and choosing" to denigrate the appellants' claimed

invention.

(9) CONCLUSION

For the foregoing reasons, Appellants respectfully request that the Honorable Board reverse the final rejections.

CONDITIONAL PETITION FOR EXTENSION OF TIME

If any extension of time for this response is required, Appellants request that this be considered a petition therefor. Please charge the required petition fee to Deposit Account No. 14-1263.

ADDITIONAL FEE

Please charge any insufficiency of fees, or credit any excess to our Deposit Account No. 14-1263.

Respectfully submitted,

Norris, McLaughlin & Marcus, P.A.

By: Howard C. Lee
Howard C. Lee
Reg. No. 48,104

220 E. 42nd Street, 30th Floor
New York, NY 10017
(212) 808-0700

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Hon. Commissioner of Patents, Washington, D.C. 20231 on the date indicated below:

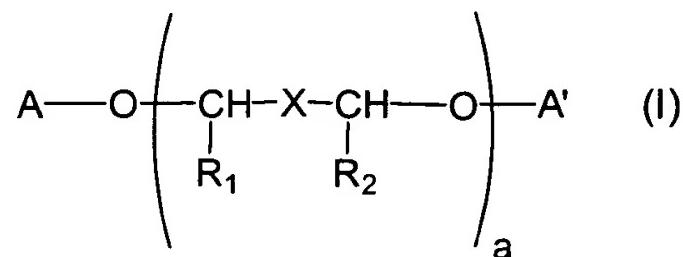
Date: 27 July 2004

By

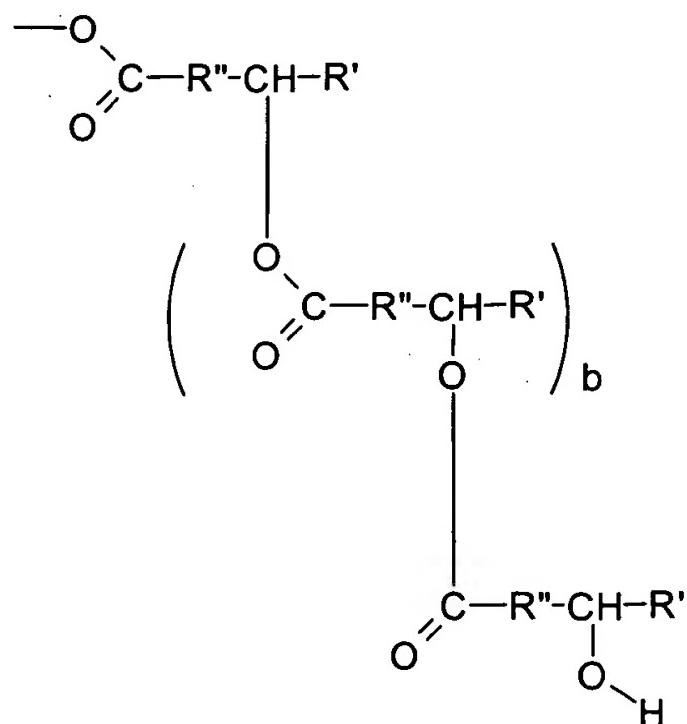
Agata Glinska
Agata Glinska

(10) APPENDIX - CLAIMS ON APPEAL

1. A water-in-oil emulsion
 - (a) with a content of water and optionally water-soluble substances totalling greater than 85% by weight, and with a content of lipids, emulsifiers and lipophilic constituents of less than 15% by weight, in each case based on the total weight of the preparations,
 - (b) comprising at least one surface-active substance selected from the group consisting of substances of the general formula (I)



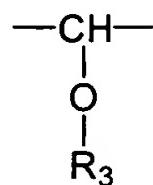
where A and A' are identical or different organic radicals selected from the group consisting of branched and unbranched, saturated and unsaturated alkyl and acyl radicals and hydroxyacyl radicals having 10 - 30 carbon atoms, and the group consisting of hydroxyacyl groups bonded together via ester functions, according to the scheme



where R' is selected from the group consisting of branched and unbranched alkyl groups having 1

to 20 carbon atoms, and R is selected from the group consisting of branched and unbranched alkylene groups having 1 to 20 carbon atoms, and b is a number from 0 to 200,

- a is a number from 1 to 100,
- X is a single bond or the group



- R₁ and R₂ independently of one another are selected from the group consisting of H and methyl,
 - R₃ is selected from the group consisting of H, and of branched and unbranched, saturated and unsaturated alkyl- and acyl radicals having 1 - 20 carbon atoms,
- (c) additionally comprising at least one cationic polymer, wherein said at least one cationic polymer is selected from the group consisting of cationic cellulose derivatized with a quaternary ammonium salt, cationic starch, copolymers of diallylammonium salts and acrylamides, quaternized vinylpyrrolidone/ vinylimidazole polymers, condensation products of a polyglycol with an amine, quaternized collagen polypeptides, quaternized wheat polypeptides, polyethyleneimine, cationic silicone polymers, copolymers of adipic acid with dimethylaminohydroxypropyldiethylenetriamine, copolymers of acrylic acid with dimethyldiallylammonium chloride, polyaminopolyamides, and cationic guar gum.

3. Emulsion according to claim 1, wherein the surface-active substance is polyethylene glycol-30 dihydroxystearate.
4. Emulsion according to claim 1, wherein the oil phase comprises at least 50% by weight of at least one substance selected from the group consisting of petrolatum, paraffin oil and polyolefins.
5. Emulsion according to claim 1, comprising from 0.01 to 10% by weight of cationic polymers.
7. Emulsion according to claim 1, wherein a is a number from 2 to 60.

8. Emulsion according to claim 7, wherein a is a number from 5 to 40.
9. Emulsion according to claim 5, wherein said amount of cationic polymers is from 0.25 to 1.25% by weight.
11. The emulsion according to claim 1 wherein the cationic cellulose derivatized with quaternium ammonium salt is polyquaternium-10.